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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,882	03/08/2004	David Radunsky	067062.0127	2882

31625 7590 11/30/2005

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EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,882	RADUNSKY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al patent 5,571,418.

Lee et al disclose a blood membrane filter or hemofilter operable to remove relatively large molecular weight complex molecules from blood with a molecular weight cutoff of 100 to kiloDaltons (column 2, lines 1-26 and 50-61 and column 4, lines 25-32 and 49-54 are especially pertinent).

If necessary, the MW cutoff of Lee et al touches the MW cutoff range described in the instant Specification at page 22, lines 6-30 (MW cutoff of 150-500 kilodalton). Since the respective ranges are touching, Lee et al is considered to anticipate the claimed range as Lee et al also teaches with specificity pore size of the membrane as effective to remove toxic substances from the blood (see ***MPEP sections 2131.03 and 2144.05).***

Claims 1,2,5-7,10 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Matson patent 6,736,972.

Patent '972 concerning a different inventive entity with an earlier effective priority date discloses for claims 1,5,6 and 11, a pharmaceutical grade fluid solvent-containing replacement fluid for therapeutic use to replace a portion of blood being hemofiltered (column 14, line 53-column 15, line 38). The fluid consists of clean, target receptor molecules including activated protein, receptor antagonists and antibodies. The fluid is formulated, in combination with the hemofiltration process, to treat various toxic medical conditions including inflammatory responses (column 15, lines 27-38 and column 16, lines 15-20 and lines 28-33)

The MW cutoff of Matson also touches the MW cutoff range described in the instant Specification at column 16, lines 10-14 (MW cutoff of 150-500 kilodalton). Since the respective ranges are touching, Matson is considered to anticipate the claimed range as he also teaches with specific pore size of the membrane as effective to remove toxic substances from the blood (see ***MPEP sections 2131.03 and 2144.05).***

For claims 2,6,11 through 17 a very large pore hemofilter 702 is used (column 16, lines 10-13).

For claims 5 and 10, the fluid may contain plural types of target receptor molecules (column 16, lines 15-18).

For claim 11, see coupling 734 and column 13, lines 1-2.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotitschke patent 4,900,720.

Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the

formulation being in solution) that is formulated to treat many toxic diseases [as with instant claims 5 and 10] (column 1 lines 37-45, etc.), and contains albumin and other receptor molecules (column 3, lines 35-52).

For claims 2 and 7, the details of hemofiltration processes do not constitute limitations for the instant composition claims.

For claims 3,4,8 and 9, the concentration of albumin or other receptor molecules may fall within the claimed concentration range as it may either constitute approximately about 5% of the solution or be at up to 35 or greater g/l (column 133, lines 14-19 and lines 35-52).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al patent 6,905,688.

Rosen et al disclose a pharmaceutical grade solution (column 4, lines 35-36 and claim 20 of Rosen) that is formulated to treat inflammatory and toxic medical conditions [as with instant claims 5 and 10] (column 186, lines 54-61, etc.), contains albumin and other receptor molecules (column 4, line 61-column 5, line 32) , binding constitutents (column 74, line 60-column 75, line 7).

For claims 2 and 7, the details of hemofiltration processes do not constitute limitations for the instant composition claims.

For claims 3,4,8 and 9, the concentration of albumin or other receptor molecules may fall within the claimed concentration range (see various examples).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahlem et al patent 6,667,299.

Ahlem et al disclose a pharmaceutical grade solution (column 22, lines 25-27) that is formulated to treat inflammatory and toxic medical conditions [as with instant claims 5 and 10] (column 22, line 66-column 23, line 4 and column 123, lines 29-30, etc.), contains albumin and other receptor molecules (column 151, lines 15-22), binding receptors (column 23, lines 57-63).

For claims 2 and 7, the details of hemofiltration processes do not constitute limitations for the instant composition claims.

For claims 3,4,8 and 9, the concentration of albumin or other receptor molecules may fall within the claimed concentration range (column 131, line 47-column 132, line 4 and column 133, lines 33-36).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,4,8,9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson in view of any one of Kotitschke, Ahlmen et al or Rosen et al.

Claims 3,4,8,9 and 11 differ from Matson in requiring the pharmaceutical grade solution to comprise a discrete concentration of albumin. However, each of Kotitschke, Ahlmen and Rosen teach use of pharmaceutical grade solutions containing albumin (see the respective foregoing 102 (b) and 102 (e) rejections of these claims. It would have been obvious to one of ordinary skill in the art to have modified the apparatus and method of Matson to include such albumin-containing solution, as taught by any of Kotitschke, Ahlmen or Rosen, so as to treat a wider variety of immune dysregulation and other inflammatory response including diseases.

Applicant's arguments filed on 11 October 2005, to the extent they continue to apply have been fully considered but they are not persuasive.

It is argued that Lee et al and Matson are assigned to the same "legal entity" or assignee. However, it is submitted that both prior art references have different inventive entities from that of the instant application and otherwise qualify as prior art, and Applicants have not taken the opportunity to present an Affidavit or Declaration to otherwise disqualify these patents as prior art.

It is also argued that neither of Lee et al or Matson teach hemofilters or ultrafilters with the claimed molecular weight cutoff (MWC). However, each of the prior art explicitly teaches MWC ranges that touch or overlap the claimed range and hence would have similar filtration properties in embodiments where the MWC touches or overlaps.

It is also argued that Matson does not disclose the use of a fluid for replacing receptor molecules as required in amended claims 1 and 6. However, the instant claims require receptor molecules that "correspond with" not "replace" contaminated or inflammatory molecules or mediators and such is indeed disclosed by Matson in column 15, lines 28-38 and column 16, lines 28-35, see especially column 16, line 31 "monoclonal antibodies" and "receptor antagonists".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

November 28, 2005

JOSEPH DRODGE
PRIMARY EXAMINER